

REMARKS

The last Office Action has been carefully considered.

It is noted that Claims 30, 32, 46, and 48-51 are rejected Under 35 USC 103(a) over the U.S. patents to Coetzee and Ryu and further in view of the U.S. patents to Owen and Drake.

Claim 31 is rejected under 35 USC 103(a) as above, and further in view of the U.S. patent to Guice.

Claims 34-35 are rejected under 35 USC 103(a) as Claim 30, and further in view of the U.S. patent to Cook.

Claim 38 is rejected under 35 USC 103(a) as Claim 30, and further in view of the U.S. patent to Connelly.

Claim 44 is rejected under 35 USC 103(a) as Claim 30, and further in view of the Japanese publication to Yomei.

Claim 45 is rejected under 35 USC 103(a) as Claim 44, and further in view of the U.S. patent to Mosby.

Claim 47 is rejected under 35 USC 103(a) as Claim 30, and further in view of the patent to Mullens.

Also, Claim 31 is objected to for formal reasons.

In connection with the Examiner's grounds for formal objections, Claim 31 has been retained as it was and explanations related thereto will be presented hereinbelow.

In view of the Examiner's rejection of the claims over the art, it is submitted that regrettably the Examiner completely repeated his opinion expressed in the last Office Action, despite the arguments presented by the Examiner in the previous Amendment, with the exception of the addition of the U.S. patent to Owen, thus actually not responding to the arguments presented by the applicants.

Before analysis of the Examiner's rejection of the claims over the prior art, it is believed to be advisable to emphasize the following:

The core of the invention is the combination of the super insulation with a maximum K-value with a cooling agent having at least a minimum "heat of melting". Only this combination creates a physical window which allows constructing a practical container which holds the

low temperature for many days and is small enough to ship with reasonable resources. The coolant is a pure organic substance showing a highly defined melting point.

This means that the inventors for the first time realized a transport container which holds the material (biological tissue samples) in a frozen state at a constant temperature for at least some days enabling a transport for example by aviation over long distances. Such a container must be absolutely impervious, compact and of light weight.

The patent to Coetzee, US 6,467,299, describes a transport container for keeping chilled pharmaceutical or veterinary preparations, which are in a liquid phase above 0°C and therefore are not frozen. According to column 4, lines 3, 4, Coetzee keeps the material at a temperature between 2 and 8°C. The same result is seen from Fig. 8, showing the temperature of the chilled material during 12 hours. Contrary to and what the Examiner says Coetzee does not mention, that the material to be chilled is frozen material as applies for the invention.

Further Coetzee has no superinsulation as conceded by the Examiner.

Contrary to what the Examiner says inner container 16 seems not to be removably arranged in the insulating chamber (in insulation 12) as is the case for the invention, where the inner container 2 can be removed from the insulation 6 for quick chilling of the exhausted refrigerant 15' after opening (own Figures 1 to 3). Fig. 2 of Coetze is an exploded view of the parts. After assembling of parts, flange 22 connects parts 12 and 16 at their upper ends as seen in Fig. 1. Therefore, according to column 3, lines 51 to 56 in order to cool down the refrigerant 14 the whole container is placed in a freezer after opening of lid 28 only, which requires a long time for cold reloading after exhaustion of the refrigerant.

It is at least questionable that the refrigerant chamber 16 of Coetze is hermetically sealed, since Coetze does not mention this feature and Fig 1 shows a sort of press fit and form fit between the upper ends of inner and outer wall of inner container 16 enclosing the refrigerant.

Further Coetze does not use a pure organic substance as refrigerant as acknowledged by the Examiner and does not work with a solid/liquid phase transformation, which guarantees a constant cooling temperature in contrast to Fig. 8 of Coetze with a continuous change of temperature including undesirable subcooling (from 8 to 2°C), and not at a constant temperature within a temperature range from -15 to -100°C. Also

it cannot be found that the refrigerant of Coetzee has a heat of melting of at least 50 J/m² as applies for the invention.

In regard to the patent to Ryu, US 6,068,682, it is correct that this reference describes a superinsulation with a very low coefficient of thermal conductivity as defined in Claim 30. However, this feature known *per se* is not the invention but only one of a plurality of features the combination of which represents the invention.

The patent to Owen, US 6,209,343, contrary to what the Examiner says does not show an inner container 10 (see figure 2) removably arranged in an insulating chamber 20a, 20b. The Examiner takes knowledge of the invention and interprets the reference in this sense. According to column 6, lines 63 to 67 of the reference the container parts are glued together.

Further in Owen the phase change material 15 is not reloaded outside the container as is the reason for removability according to the invention. Instead of this, Owen provides cut outs 15a (Fig. 2) for introducing a cryogenic material in order to reload the phase change material 15 (column 6, lines 47 to 51).

The patent to Drake, US 3,858,410, is introduced by the Examiner in view of the feature of using an organic substance as the phase change material. Owen proposes to use mercury as a phase change material, but mercury is a metal and is far away from being an organic substance. It is incredible that the Examiner is still insisting that mercury is an organic substance. It is not understood whether he familiarized himself with applicants Amendment.

The same impression could be derived from the objection of Claim 31 on page 2 of the Final Action. A reference is made to the embodiment of Figure 19 with an "additional jacket" and a "refrigerant melting at a higher temperature" (See page 5, lines 28 to 31) as described in detail on pages 12 and 13. It can be only repeated that Claim 31 claims two different refrigerants 71' and 78' with two different temperatures of phase change – i.e. -15 to -100°C according to main Claim 30 and 0 to -15°C according to Claim 31, which are arranged in series in order to divide the gradient of temperature between environment and the frozen material. Nothing of this tandem arrangement is described in Guice.

It is believed to be clear that none of the references disclose the new features of the present invention as defined in Claim 30, and these new features could not be derived from the combination of the

references since they do not contain any hint, suggestion or motivation for such features.

In order to arrive at the applicant's invention from the prior art applied by the Examiner, the references have to be fundamentally modified, and in particular by including into them the new features of the present invention as defined in Claim 30 and which were first proposed by the applicants. However, it is known that in order to arrive at a claimed invention, by modifying the references the cited art must itself contain a suggestion for such a modification.

This principle has been consistently upheld by the U.S. Court of Customs and Patent Appeals which, for example, held in its decision *In Re Randol and Redford* (165 USPQ 586) that:

Prior patents are references only for what they clearly disclose or suggest, it is not a proper use of a patent as a reference to modify its structure to one which prior art references do not suggest.

It should be mentioned that the Examiner's objection based on the combination of the reference cannot be considered as justified, since the use of so many references clearly shows that the present invention cannot be obvious and it was necessary to take pieces from the references to provide an unacceptable piecemeal reconstruction of the

present invention, based on the fact that the Examiner is familiarized with the subject matter of the present invention.

It should be also mentioned that Claim 30 defines the additional features of a.) frozen transported material, b.) removable arrangement of the inner container, c.) permanently hermetically sealed refrigerant chamber, d.) using a pure organic substance as refrigerant, e.) maintaining the range of -15 to -100°C as constant chilling temperature and f.) a refrigerant with a heat of melting of at least 50 J/ml.

These features are plainly not disclosed in the references.

Also, as explained hereinabove, the present invention provides for the highly advantageous results which cannot be accomplished by the devices disclosed in the references. It is well known that in order to support a valid rejection the art must also suggest that it would accomplish applicant's results. This was stated by the Patent Office Board of Appeals, in the case *Ex parte Tanaka, Marushma and Takahashi* (174 UPSQ 38), as follows:

Claims are not rejected on the ground that it would be obvious to one of the ordinary skill in the art to rewire prior art devices in order to accomplish applicant's result, since there is no suggestion in prior art that such a result could

be accomplished by so modifying prior art devices.

In view of the above presented remarks and amendments, it is believed that Claim 30, the broadest claim on file, should be considered as patentably distinguishing over the art and should be allowed.

As for some dependent claims, applicants wish to make the following remarks.

The patent to Guice, US 5,355,684, describes a vessel for storage or shipment of frozen biological materials 26 using one (Fig. 4 or 5) or more (Fig. 2 or 3) heat sink bars 28 using phase change and being reloaded outside (Fig. 2 and 4) or inside (Fig. 3 and 5) of the vessel. Guice is cited against Claim 31. According to this claim two refrigerants with different temperatures of phase change – i.e. -15 to -100°C according to main Claim 30 and 0 to -15°C according to Claim 31 – are arranged in series in order to divide the gradient of temperature between environment and the frozen material. Nothing of this tandem arrangement is described in Guice.

Cook, US 5,934,099, describes a container for storing and transporting vessels containing temperature sensitive material like pharmaceuticals. Again a heat sink is used. The interpretation of Cook by

the Examiner is correct in view of page 6, paragraph 3 of the Official action, see "sonic welding" in column 6, lines 58, 59 for closing the refrigerant chamber. This applies to Claim 35. But the next paragraph is incorrect since there is only one and no additional refrigerant chamber.

As for other dependent claims, these claims depend on Claim 30, they share its allowable features, and they should be allowed.

Reconsideration and allowance of the present application is most respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects in order to place this case in condition for final allowance, then it is respectfully requested that such amendments or corrections be carried out by Examiner's Amendment, and the case be passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, he is invited to telephone the undersigned (at 631-549-4700).

Respectfully submitted,



Michael J. Striker
Attorney for Applicants
Reg. No. 27233